K 121351

AUG 29 2012

510(k) Number _____

510(k) SUMMARY

ENTrigue Surgical's Sinus Dilation System

Date Prepared:	May 3, 2012
Trade Name:	*ENTrigue*® Sinus Dilation System
Sponsor:	ENTrigue Surgical, Inc. 12672 Silicon Drive, Suite 150 San Antonio, Texas 78249 USA Telephone: 1-877-300-5010 Fax: 1-210-298-6399 Contact Person: Gabriele G. Niederauer, Ph.D.
Product Code and Device Classification Name:	LRC Sinus Dilation System (21 C.F.R. § 874.4420)
Classification:	Class I (exempt from 510(k) requirements)
Predicate Device:	Entellus Medical, Inc. XprESS™ Multi-Sinus Dilation Tool [K102003]
Intended Use:	The ENTrigue® Sinus Dilation System is intended for use in surgical procedures to access, examine or treat the nasal and paranasal tissues leading to ostia.
Indications for Use:	The Sinus Dilation Balloon System is indicated to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach.
Technological Characteristics:	The *ENTrigue*® Sinus Dilation System consists of a disposable balloon which is mounted on a reusable delivery instrument to allow for dilation of sinus ostia in the paranasal cavity under endoscopic guidance. The Sinus Balloon components include a balloon sleeve to slide over the tip of the delivery instrument, a connecting collar to latch the balloon sleeve to the delivery instrument, and an inflation line to connect to the balloon inflation device. The features of this device enable a physician to guide the device to the sinus ostium using endoscopic visualization. The *ENTrigue*® Sinus Balloon Dilation Balloon and inflation device are individually packaged and provided sterile for single use only. The delivery instrument is a reusable instrument which must be sterilized prior to use following the

recommended and validated cleaning and sterilizing procedures.

Performance Data:

Bench and cadaveric testing,fea turing multiple users, was conducted to validate that the instrument design met user requirements and confirmed that the *ENTrigue*® Sinus Dilation System is substantial equivalent to the legally marketed predicate device; the XprESS™ Multi-Sinus Dilation Tool. Biocompatibility, sterilization, packaging, distribution, and shelf life testing were also submitted. In all instances, the *ENTrigue*® Sinus Dilation System functioned as intended and the results observed were as expected.

Substantial Equivalence:

The *ENTrigue*® Sinus Dilation System is as safe and effective as the Entellus Medical, Inc. XprESS™ Multi-Sinus Dilation Tool. The *ENTrigue*® Sinus Dilation System has the same intended uses and similar indications, technological characteristics (design, materials), principles of operation, packaging and sterilization (EtO) as the predicate device. The minor technological differences between the *ENTrigue*® Sinus Dilation System and its predicate device do not constitute differences in fundamental scientific technology. Performance data demonstrate that the *ENTrigue*® Sinus Dilation System is as safe and effective as the Entellus Medical, Inc. XprESS™ Multi-Sinus Dilation Tool. Thus, the *ENTrigue*® Sinus Dilation System is substantially equivalent to the XprESS™ Multi-Sinus Dilation Tool.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ENTrigue Surgical, Inc.
c/o Gabriele G. Niederauer, Ph.D.
Senior Vice President, Technology and Development
12672 Silicon Drive, Suite 150
San Antonio, TX 78249

AUG 29 2012

Re: K121351
Trade/Device Name: ENTrigue® Sinus Dilation System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: July 31, 2012
Received: August 9, 2012

Dear Dr. Niederauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

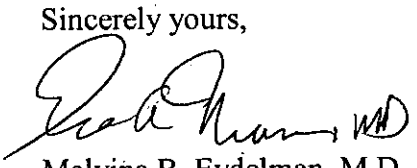
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 12 135 |

Indications for Use Statement

510(k) Number (if known): _____

Device Name: ENTrigue® Sinus Dilation System

Intended Use:

The ENTrigue® Sinus Dilation System is intended for use in surgical procedures to access, examine or treat the nasal and paranasal tissues leading to ostia.

Indications for Use:

The ENTrigue® Sinus Dilation System is indicated to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K12135 |